

## REMARKS/ARGUMENTS

Reconsideration of the present application, as amended, is respectfully requested.

### **A. STATUS OF THE CLAIMS**

As a result of the present amendment, claims 3, 7-12 and 14-22 remain in the case for continued prosecution. Claim 3 has been amended to include the subject matter of claims 5 and 6. Claim 3 has also been amended to correct informalities as suggested by the Examiner. Claims 5-6 and 13 are cancelled without prejudice. Claims 7-8 have been amended to correspond to the recitation of claim 1 as amended herein. Claim 11 has been amended to recite "polyphosphates, phosphonates" as suggested by the Examiner. New dependent claims 16-22 have been added to set forth additional aspects of what Applicants consider to be their invention. Support for claim 16 can be found, for example, at page 19, lines 1-6 and at page 20, Table 1. Support for claim 17 can be found, for example, at page 19, lines 7-12 and at page 20, Table 1. Support for claims 18-19 can be found, for example, at page 18, lines 5-8. Support for claims 20-21 can be found, for example, at page 18, lines 9-11. Support for claim 22 can be found, for example, at page 25, lines 16-18 and at page 24, Table 3. No new matter has been added.

### **B. INFORMALITIES**

The Examiner noted informalities in claims 3 and 13. As a result of the amendments to claims 3 and 13, all informalities mentioned by the Examiner are corrected.

### **C. ALLOWABLE SUBJECT MATTER & DUPLICATE CLAIM WARNING**

Claim 13 has been objected to as allegedly being a duplicate of claim 3. In response, without admitting the position of the Examiner and for the purpose of facilitating the prosecution, claim 13 has been cancelled without prejudice. Thus, the objection to claim 13 is now moot.

### **D. INDEFINITENESS REJECTION**

Claim 11 is rejected under 35 USC 112, second paragraph, as allegedly indefinite.

Claim 11 as amended herein recites “polyphosphates, phosphonates” as suggested by the Examiner. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested

**E. OBVIOUSNESS REJECTION**

All pending claims are rejected under 35 USC 103(a) as allegedly unpatentable over Singh et al. (US Pub. 2004/0105834). The Examiner has alleged that “It would have been obvious to have included any of these conventional agents for their art-recognized purposes per these teachings”. See last sentence of the first paragraph on page 6 of the Office Action. The Examiner has also alleged that “Accordingly, it would have been obvious to have varied the thicknesses of the various sublayers of the prior art strips to tailor them to particular uses and thus to have arrived at the instantly claimed values in doing so, motivated by the desire to determine optimal and/or workable thicknesses through the application of routine experimentation per the reasoning of the cited precedent”. See the last sentence of the last paragraph on page 6 of the Office Action.

Applicants respectfully disagree. Applicants respectfully submit that a proper *prima facie* rejection of obviousness cannot be established based on Singh et al. It is respectfully submitted that the Examiner has not provided specifics concerning how the claimed erodible tooth whitening patches would be made based on the teachings of Singh et al.

Singh et al. discloses solid and non-solid, i.e. liquid, hydrogel compositions. Only the solid hydrogel composition is pertinent to the analysis of the obviousness rejection. The solid composition includes (i) a water-swellable, water-insoluble polymer and (ii) a blend of a hydrophilic polymer and a complementary oligomer, and (iii) an optional active agent such as a tooth whitening agent. The water-swellable polymer can be (meth)acrylate polymers including Eudragit® series E, L, S, etc. The blend of the hydrophilic polymer and the complementary oligomer can be PVP mixed with polyethylene glycol (PEG).

Singh et al. discloses further including a backing member. The Examiner has taken the position that it would have been obvious for those of ordinary skill in the art to

mix polymers listed for the backing member and arrive at the claimed erosion rate-controlling layer. See page 5, last paragraph of the Office Action.

Descriptions pertinent to the backing member in Singh et al. are as follows:

[0134] The erodible backing member is comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel and is substantially non-tacky. There are numerous materials that can be used for the backing member, and include, by way of example, and not limitation, acrylate polymers, cellulose derived polymers, cellulose esters, starches, alginic acid, alginates, polyamino acids. Combinations, i.e., Blends of any of these different polymers can also serve as backing member material.

[0136] ... For example, if L 100-55 is selected for use in the hydrogel, Eudragit L 100 can be used in the backing; if Eudragit L 100 is used in hydrogel, Eudragit S 100 could be used in the backing; and so forth. In addition, mixtures of Eudragit polymers or mixtures of Eudragit polymers with other polymers and excipients (e.g. buffering agents, pH modulators) may be used to tailor the rate of erosion of the backing member relative to the hydrogel.

[0137] Suitable cellulose derived polymers include by way of example and not limitation, hydratecellulose (cellophane), methyl cellulose, ethyl cellulose, hydroxyethyl cellulose (HEC), hydroxypropylcellulose (HPC), hydroxypropylmethylcellulose (HPMC), carboxymethylcellulose (CMC), and sodium carboxymethylcellulose (Na--CMC). Preferred celluloses are hydratecellulose, methyl cellulose, ethyl cellulose, hydroxyethyl cellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, carboxymethylcellulose, sodium carboxymethylcellulose, and mixtures thereof.

*Emphasis added.*

Thus, contrary to the Examiner's, there is no mention in the reference that teaches or suggests that it would have been obvious to those of ordinary skill in the art to modify the solid compositions of the reference to arrive at the claimed invention including the specific amount ratio of the two ingredient polymers in the erosion rate-controlling layer. Unlike the Examiner's position that artisans would have arrived at the claimed erosion rate-controlling layer according to the teachings of Singh et al., such speculation at best invites one to experiment or provides an invitation to try various steps with hope that one would serendipitously stumble upon the claimed invention. The Examiner's position is unfounded hindsight.

On the other hand, the present invention provides erodible tooth whitening patches. The patches as amended herein include (1) a tooth-adhering layer and (2) an erosion rate-controlling layer. The tooth-adhering layer and the erosion rate-controlling layer in combination allow controlling erosion rate of the claimed tooth whitening patches. The tooth-adhering layer includes erodible polymer complexes formed by hydrogen bonding of (meth)acrylic acid copolymer and polyvinylpyrrolidone (PVP) and a tooth whitening agent. The (meth)acrylic acid copolymer ranges from about 1 weight % to 10 weight % and the PVP ranges from about 40 weight % to about 80 weight % of the total dry weight of the tooth-adhering layer, respectively. The erosion rate-controlling layer includes hydroxypropyl cellulose (HPC) and a (meth)acrylic acid copolymer. In the erosion rate-controlling layer, the HPC ranges from about 10 weight % to about 60 weight % and the (meth)acrylic acid copolymer ranges from about 5 weight % to about 65 weight % of the total dry weight of the erosion rate-controlling layer, respectively.

As such, the burden for the obviousness rejection has not been met. Reconsideration and removal of the rejection is respectfully requested.

In the event that the Examiner takes that position that a *prima facie* case of obviousness has been made, Applicants have provided sufficient evidence of unexpected results that would rebut the case. As agreed by the Examiner and stated in the Advisory Action dated January 12, 2007, the erosion rate-controlling layer including the specific amounts of the HPC and (meth)acrylic acid copolymer in combination with the tooth-adhering layer provides unexpected and superior results over art-known tooth patches, i.e. sufficient attachment to the teeth and erosion thereafter. See page 2 of the Advisory Action. The claimed patches attach firmly to the teeth and erode from 30 minutes to about 3 hours after application to the teeth. On the other hand, art-known patches including comparative patches either prematurely detach from the teeth, i.e., within 30 minutes from application to the teeth or do not erode. See, for example, unexpected and superior results of Inventive Examples 1-9 compared to those of Comparative Examples 1-5 and Controls 1-2 (which are art-known patches) on page 24, Table 3 of the specification. Their relative compositions are described on page 20, Table 1 for

Inventive Examples 1-9; page 22, Table 2 for Comparative Examples 1-5; and paragraphs bridging pages 22-23 for Controls 1-2.

In order to provide the unexpected superior erosion rate-controlling layer, the specific amount ratio of the HPC and (meth)acrylic acid copolymer, i.e. each 10 weight %-60 weight % and 5 weight %-65 weight % of the total dry weight of the erosion rate-controlling layer, is important. If the amount of the HPC is less than 10 weight %, the erosion rate reduces. On the other hand, if the amount of the HPC is higher than 60 weight %, the erosion rate-controlling layer erodes too fast. See page 12, lines 19-24 of the specification. Similarly, if the amount of the (meth)acrylic acid copolymer is less than 5 weight %, the erosion rate-controlling layer erodes before the tooth whitening agent is sufficiently released. If the amount of the (meth)acrylic acid copolymer is higher than 65 weight %, the erosion rate-controlling layer does not erode and thus, remains on the surface of the teeth unnecessarily and is required to be removed from the teeth. See page 13, lines 6-12 of the specification. As such, it is advantageous that the claimed patches allow release of sufficient amount of the tooth whitening agent, prevent immature detachment of the patches, and eliminates the need to remove the patches from the teeth.

Singh et al. discloses embodiments of the solid composition in Example 1.

Paragraphs [0173]-[0174] of Example 1 are as follows:

#### Example 1 Preparation of a Solid Composition

[0173] One embodiment of a composition for tooth whitening can be prepared from the following ingredients using a melt extrusion process:

Eudragit L 100-55	9 wt %
PVP	44 wt %
PEG 22 wt %	44 wt %
Hydrogen peroxide	6 wt %
Water, stabilizers, pH modulators	19 wt %

[0174] The ingredients are melt processed in a Brabender single screw extruder as follows: The Eudragit L 100-55 is added to the extruder first, followed by PVP and PEG, at a temperature of 100 to 150 °C. The composition is extruded to a thickness of 0.35 mm between a polyethylene terephthalate release liner and an erodible backing member made of Eudragit S 100 with appropriate plasticizer if needed. Hydrogen peroxide solution was added to the extruded film.

The solid composition includes Eudragit S100 as the backing member. Unlike the claimed erodible rate-controlling layer, it is urged that the backing member employing Eudragit S100 does not erode and thus it is required to be removed from the teeth after a certain period of time. In fact, it is urged that the backing member employing Eudragit S100 of the reference is used to prevent erosion.

As such, those skilled in the art would not have predicted that the specific amounts of the HPC and (meth)acrylic acid copolymers, i.e., each 10 weight %-60 weight % and 5 weight %-65 weight % of the total dry weight of the erosion rate-controlling layer, would provide superior results in controlling superior erosion-rate. Accordingly, the claimed invention as amended herein is distinguished over Singh et al. and any references relied upon by the Examiner. Reconsideration and withdrawal of the rejection is respectfully requested.

Additionally, it should be appreciated that the claimed invention is a dry film. The specification teaches that water in the inventive device is eliminated by drying. Water and solvents are dried in both tooth-adhering layer and erosion rate-controlling layer. The two dried layers are then laminated and dried again to remove water and solvents therein. See page 19, lines 14-21 of the specification. Therefore, a small amount of water on the surface of the teeth allows the tooth-adhering layer of the claimed invention to be sufficiently adhesive and firmly attach to the teeth. Unlike the claimed invention, the patch of Singh et al is prepared by an extrusion process. It is not dried and contains approximately 19% water as stated above. The patch of the reference has lower adhesiveness due to a large quantity of water contained. Therefore, it is urged that the patch of the reference does not attach to the teeth sufficiently.

Alternatively and/or additionally, an English translation of the Korean priority application, KR 2003-0027455 filed April 30, 2003 is being submitted herewith for the Examiner's consideration. The Examiner's attention is respectfully directed to the description on page 11, first paragraph of the English translation, which indicates that the erosion rate-controlling layer and tooth-adhering layer of the claimed invention (referred to as an erodible drug layer) has been reduced to practice before Singh et al. relied upon by the Examiner for the obviousness rejection. The parent application for Singh et al. is

US Patent Appl. Ser. No. 10/137,664 filed on May 1, 2002. The parent application does not disclose an erodible backing member.

For all the reasons set forth above, it is respectfully submitted that the claimed invention is not obvious over Singh et al. and any references made of record by the Examiner. Reconsideration and withdrawal of the rejection is respectfully requested.

**F. FEES**

This response is being filed within a one-month extension of time and the required fee via credit card authorization. Thus, no further fee is believed to be required. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

**G. CONCLUSION**

In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner have been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

LUCAS & MERCANTI, LLP

By:   
Hyun Soon Cho  
Recognition No. L0306

LUCAS & MERCANTI, LLP  
475 Park Avenue South  
New York, New York 10016

Phone: 212-661-8000

Fax: 212-661-8002